

REMARKS

In view of the following remarks, the Examiner is requested to allow claims 1-23 and 25-29, the only claims under examination in this application.

Claims 1, 10, 25 and 26 have been amended. Claims 1, 25 and 26 have been amended to indicate that water-soluble contrast agent is incorporated into the calcium phosphate product. Support for these amendments may be found at page 6, line 30 to page 7, line 2. Claim 10 has been amended to clarify that the indicated ratio is a dry reactant to setting fluid ratio. Accordingly, no new matter has been added.

As no new matter has been added by way of these amendments, entry thereof by the Examiner is respectfully requested.

Claim Rejections - 35 USC § 112, second paragraph

Claims 1 and 10 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office asserts that Claim 1 is ambiguous because it is assertedly unclear what the Applicants intend by the phrase "sets into." The Applicants disagree. The Applicants contend that when viewed in light of the specification as a whole it is clear that the phrase "sets into" means that the flowable composition solidifies (i.e., sets) into a calcium phosphate product. See for instance, page 14, lines 11 – 14. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

The Office asserts that Claim 10 is ambiguous because it is unclear as to which components the disclosed range is directed. The Applicants have amended Claim 10 to

clarify that the indicated ratio is a dry reactant to setting fluid ratio thus obviating this rejection. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Claim Rejections - 35 U.S.C. § 102

Claims 1-7, 11, 14-17, 20, 22 and 23 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Wenz (WO 2004/050131).

According to the M.P.E.P., a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. The identical invention must be shown in as complete detail as is contained in the claim. See M.P.E.P. 2131.

The claims as amended include a composition that sets into a calcium phosphate containing product. An element of the amended claims is a water-soluble contrast agent **that is incorporated into the calcium phosphate product.**

Wenz does not teach the use of a water-soluble contrast agent that is incorporated into the calcium phosphate. Accordingly, the Applicants respectfully request that the 35 U.S.C. § 102(e) rejection of Claims 1-7, 11, 14-17, 20, 22 and 23 be withdrawn.

Claim Rejections - 35 U.S.C. § 103

Claims 1, 7-10, 13, 15, 18, 21, 25 and 26 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wenz in view of Constantz *et al.* (USPN 6,334,891).

According to the M.P.E.P. § 706.02 (j), to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

As previously stated, an element of the claims as amended is a water-soluble contrast agent that is incorporated into the calcium phosphate product. Wenz is deficient in that it does not teach or suggest this element of the claims. Wenz does not suggest this element because Wenz teaches the use of water-soluble radioopacity agents that leak out of and are eliminated from the cement product after being applied to the desired target site. See page 8, lines 11 to 16. As Constantz was cited solely for its disclosure of various components that may be included in a kit it fails to remedy the deficiencies of Wenz.

Accordingly, the Applicants contend that a *prima facie* case of obviousness has not been established because the combination of Wenz and Constantz does not teach every element of the claimed invention, namely, a water-soluble contrast agent that is incorporated into the calcium phosphate product. Therefore, the Applicants respectfully request that the 35 U.S.C. § 103(a) rejection of Claims 1, 7-10, 13, 15, 18, 21, 25 and 26 be withdrawn.

Double Patenting

Claims 1-23 and 25-29 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-11 and 14-18 of copending U.S. Patent Application No. 10/851,766.

The Applicants respectfully disagree. As stated above, an element of the amended claims is a water-soluble contrast agent that is incorporated into the calcium phosphate so as to form a stable calcium phosphate containing product. U.S. Patent Application No. 10/851,766 does not teach or suggest a water-soluble contrast agent that is incorporated into the calcium phosphate product. Accordingly, the Applicants respectfully request that the provisional obviousness-type double patenting rejection of Claims 1-23 and 25-29 be withdrawn.

CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number SKEL-007.

Respectfully submitted,
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By: _____


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